## Message Text

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USDA: GHEIMPEL

E.O. 11652: N/A

TAGS: ETRD, ES

SUBJECT: GOES REGULATIONS ON PROCESSED FOOD AND BEVERAGE IMPORTS

REF: SAN SALVADOR 2095

1. PROCESSED FOOD AND BEVERAGE PRODUCTS PRODUCED IN THE U.S. MAY BE EXPORTED WITHOUT RESTRICTION IF THEY MEET STANDARDS FOR DOMESTIC SALE. IN ACCORDANCE WITH SECTION 801 (D) OF THE FOOD, DRUG AND COSMETIC ACT OF 1976 AS AMENDED BY SECTION 106 OF P.L. 90-399 AND SECTION 3(F) OF P.L. 94-295, SUCH A PRODUCT MAY ALSO BE EXPORTED EVEN THOUGH IT DOES NOT MEET U.S. STANDARDS IF IT -

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"(A) ACCORDS TO THE SPECIFICATIONS OF THE FOREIGN PURCHASER,

(B) IS NOT IN CONFLICT WITH THE LAWS OF THE COUNTRY TO WHICH IT IS INTENDED FOR EXPORT,

(C) IS LABELED ON THE OUTSIDE OF THE SHIPPING

PACKAGE THAT IT IS INTENDED FOR EXPORT, AND

(D) IS NOT SOLD OR OFFERED FOR SALE IN DOMESTIC COMMERCE."

FYI: WHILE FDA HAS THE LEGAL AUTHORITY TO REQUIRE EXPORTERS TO DEMONSTRATE COMPLIANCE WITH THE IMPORTING COUNTRIES' LAWS AND REGULATIONS, IN PRACTICE THAT RESPONSIBILITY IS LEFT TO THE OFFICIALS OF THE IMPORTING COUNTRY. END FYI.

- 2. FDA DOES NOT ISSUE A "CERTIFICATE OF FREE SALE" FOR ARTICLES FOR EXPORT. A FACTUAL STATEMENT OF THE STATUS OF A SPECIFIC ARTICLE SUBJECT TO FDA JURISDICTION MAY BE PROVIDED BY THE FDA UPON REQUEST. FOR AN ARTICLE NOT SUBJECT TO PREMARKET CLEARANCE (E.G. FOOD) A STATEMENT THAT ITS FORMULATION AND LABELING MEET THE REQUIREMENTS OF THE ACTS FDA ENFORCES MAY BE PROVIDED BY THE FDA IF THE COMPLETE QUANTITATIVE FORMULA, FULL LABELING AND OTHER INFORMATION REQUIRED TO EVALUATE THE ARTICLE'S STATUS ARE SUBMITTED BY THE REQUESTOR.
- 3. THE STATEMENT WILL BE ISSUED BY FDA IN LETTER ADDRESSED "TO WHOM IT MAY CONCERN." WHEN NECESSARY, AND UPON SPECIFIC REQUEST, THE STATEMENT MAY BE A CERTIFIED COPY UNDER SEAL OF THE DEPARTMENT OF HEALTH, EDUCATION AND UNCLASSIFIED

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WELFARE. A CERTIFIED COPY UNDER SEAL AUTHENTICATES THE LETTER AS A DOCUMENT ISSUED BY THE FOOD AND DRUG ADMINISTRATION; IT DOES NOT CONSTITUTE A CERTIFICATION OF THE ARTICLE ITSELF IN ANY RESPECT.

4. FDA HAS NO OBJECTION TO AN EXPORTER WHO REQUIRES A "CERTIFICATE OF FREE SALE" OBTAINING A STATEMENT FROM A TRADE OR COMMERCIAL ORGANIZATION WHICH CERTIFIES THAT A PRODUCT IS FREELY SOLD IN U.S. COMMERCE. ANY SUCH STATEMENT THAT THE ARTICLE IS IN CONFORMITY WITH THE LAW IS AT THE RESPONSIBILITY OF THE ISSUING ORGANIZATION.

FYI: PARAGRAPHS 2-4 WERE TAKEN FROM FDA COMPLIANCE POLICY GUIDE 7150.02. END FYI.

5. WE RECOGNISE A GOVERNMENT'S RIGHT AND RESPONSIBILITY TO PROTECT ITS CITIZENS FROM HEALTH HAZARDS BY SETTING STANDARDS FOR THE FOOD AND BEVERAGE PRODUCTS THEY CONSUME. HOWEVER, THOSE STANDARDS SHOULD NOT BE ADMINISTERED IN SUCH A WAY THAT THEY UNNECESSARILY RESTRICT TRADE AND/OR UNFAIRLY DISCRIMINATE AMONG SUPPLIERS. DEPARTMENT IS CURRENTLY REVIEWING VARIOUS TREATIES INVOLVED IN THE

CURRENT SITUATION AND WILL ADVISE EMBASSY FURTHER IF THEY OFFER ANY SOLUTION TO PROBLEM. (WE WOULD APPRECIATE IF EMBASSY WOULD POUCH A COPY OF THE EL SALVADOR-PANAMA BILATERAL MENTIONED REFTEL.) IN THE INTERIM, EMBASSY SHOULD, IF IT HAS NOT ALREADY DONE SO, REQUEST AN EXEMPTION FROM LABORATORY VERIFICATION REQUIREMENT FOR U.S. ORIGIN PRODUCTS. IN RAISING THIS MATTER WITH THE GOES EMBASSY MAY WISH TO POINT OUT THAT THESE STANDARD REQUIREMETS SEEM TO BE ERECTING THE VERY SAME KINDS OF TRADE BARRIERS WHICH THE GOES IS COMMITTED TO REDUCING AS A PARTICIPANT IN THE MULTILATERAL TRADE NEGOTIATIONS IN GENEVA. CHRISTOPHER

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